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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,548	07/16/2003	Robert Flower	14398	5957

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Ralph A. Dowell
Dowell & Dowell P.C.
Suite 309
1215 Jefferson Davis Highway
Arlington, VA 22202

EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,548	FLOWER, ROBERT	
	Examiner	Art Unit	
	Henry M Johnson, III	3739	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *061804*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

On page 9, line 17, a word is missing.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3 and 10-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 66 and 76 of copending Application No. 10/034432. Although the conflicting claims are not identical, they are not patentably distinct from each other because except for minor wording alterations, they are essentially identical.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 6-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2003/0060718 to Alam et al. (Alam). Alam discloses indocyanine green (ICG) compositions useful for angiography, dye-enchanced photocoagulation and photodynamic therapy for a variety of conditions including age related macular degeneration (abstract). The ICG is a liposomal ICG formulation (paragraph 0034). In ophthalmic angiography, the ICG is excited to fluorescence by radiation, permitting angiograms of the ophthalmic vasculature to be obtained (paragraph 0004). When administered in connection with angiography, the relatively high concentration ICG formulations (step ii) of the present invention permit more rapid and accurate identification of vessels, e.g., vessels that feed blood to a lesion (step i). When treatment of the feeder vessel or lesion, such as a tumor or CNV, via dye-enhanced photocoagulation (step iii) is desired, the inventive compositions provide faster and more permanent occlusion of these abnormalities (0009). Conventional radiation treatment, mentioned previously, surgical intervention, and photodynamic therapy (PDT, the latter using the inventive ICG compositions, under conditions which produce, as presently theorized, the production of singlet oxygen which damages the targeted tissue) may also be used (step iv) individually or in combination, before, after and in some cases, if feasible, during, the diagnostic and/or treatment methods of the present invention have been used. Preferably, PDT is applied after the dye-enhanced photocoagulation therapy described herein, and more preferably without further administration of ICG (paragraph 0054).

Regarding claim 4, the radiation is disclosed as applied as the dye bolus first enters the vessel to be treated (paragraph 0052) thus implying the dye is administered as a bolus.

Regarding claim 6, the same ICG composition may be administered to a given patient over a course of several days (paragraph 0007).

Regarding claims 22-25, Alam teaches the use of angiographics at various stages of the treatment of vessels. The applicant cites the same steps for determining the rate the composition exits the lesion as for the other visualizations. It is implicit the angiographic images of Alam can be used for this purpose.

Claims 1-3 and 6-11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,440,950 to Zeimer. Zeimer teaches a method of occluding vasculature in the mammalian eye involving the steps of: administering intravenously heat-sensitive liposomes having encapsulated within a fluorescent dye; irradiating a pre-determined anatomical locus within the eye with a first laser beam in order to selectively and non-invasively heat the vasculature and cause the liposomes accumulated therein to release their contents; identifying abnormal blood vessels or sinuses and a blood flow origin (step i) within abnormal vasculature by visualizing an advancing blood/dye boundary within the feeder vessel supplying blood to the vascular abnormality; and, occluding the feeder blood vessel with a second laser beam focused on the blood/dye boundary. The term "blood/dye" boundary describes an interface, i.e., a discernible point of distinction, between non-fluorescent filling blood, i.e., freshly entering blood devoid of released dye, and draining blood, i.e., fluorescent blood into which dye and/or tissue-reactive agents had been earlier released. The blood/dye boundary need not be sharply delineated to be successfully identified and localized. A "feeder blood vessel" refers to a vessel or complex of vessels which supplies blood to a particular system of vasculature at a particular anatomical locus. A feeder blood vessel may supply a normal vascular system with blood, or alternatively it may supply an abnormal vascular system with blood. This particular

embodiment of the invention contemplates at least two different modes of occlusion using a second laser beam. The first mode involves a second heating laser beam (step iii) which is effective to cause heat damage to the feeder blood vessel such that the vessel is coagulated and occluded (Col. 13, lines 1-35). Zeimer further teaches that the fluorescent dye is also a tissue-reactive agent (step ii, Col. 13, lines 58-60) and that the tissue-reactive or photosensitive agent may be activated via laser (step iv) during its very short presence in the vessel lumen after its release from the heat-sensitive liposomes to occlude the vessels (Col. 22, lines 1-3). The methods are disclosed for addressing macular degeneration and choroidal neovascularization (Col. 8, lines 46-56). Indocyanine green is disclosed as a suitable fluorescent dye (Col. 6, lines 59-60).

Regarding claims 6 and 7, Zeimer teaches the criticality of the timing due to clearance of the agent from tissue to preclude damage to the choriocapillaris making these factors implicit in the methods.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0060718 to Alam et al. (Alam) as applied to claims 1-4 above and further in view of U.S. Patent 5,707,986 to Miller et al. (Miller). Alam is discussed above, but does not teach the administration of the ICG in a bolus followed by a saline flush. Miller discloses ICG as a dye in angiographic observation in an eye (Col. 6, lines 112-16) wherein the

administration is preferably by intravenous injection of a bolus followed by a saline flush (Col. 6, lines 31-33).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,443,976 to Flower et al. discloses ICG with dye-enchanced photocoagulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994 (571.272.4764 after 11/8). The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Henry M. Johnson, III
Patent Examiner
Art Unit 3739